fluid in a recirculating fluid loop with fluid from a thermal reservoir to achieve a selected fluid temperature in the recirculating fluid loop. Because temperature control is achieved by mixing reservoir fluid with recirculating fluid a high flow rate and a high delivery pressure can be used regardless of the selected temperature; this results in a relatively small temperature differential across the thermal pad and provides greater control over the thermal therapy applied across the therapy site. The invention also controls the temperature of the fluid injected into the inlet of the thermal pad, enabling a patient to use the thermal pad for extended periods of time without risk of tissue damage from prolonged exposure to excessive heat or cold at the fluid inlet of the thermal pad.

The Examiner has rejected claims 8-18 under 35 USC § 112, first paragraph. In particular, the Examiner has indicated that

> The disclosure fails to teach one skilled in the art, the operation of the pump/heat exchanger and how it cooperates in combination with the other elements. Neither the written description or the drawings gives sufficient information on the operation of the pump/heat exchanger.

Contrary to the Examiner's assertion, however, the specification provides sufficient information for a person skilled in the art to make and use the invention without undue experimentation.

Referring to Fig. 2, the thermal therapy device includes a thermal reservoir 19, a pump/heat exchanger 13, a priming valve 14, an outlet 11 for delivering temperature-

controlled fluid to a thermal pad (not shown), an inlet 12 for receiving fluid returning from the thermal pad, and an air/water separator 15. As explained in detail below, the disclosure describes the cooperation of the pump/heat exchanger with the other elements as follows: (1) the pump/heat exchanger receives fluid from thermal reservoir 19 and fluid returning from the thermal pad; (2) the pump/heat exchanger replaces a selected amount of recirculation fluid with reservoir fluid to achieve a selected recirculation fluid temperature; and (3) the pump/heat exchanger delivers pressurized fluid to the thermal pad to complete the fluid flow path.

(1) The disclosure explains that the pump/heat exchanger receives fluid from the reservoir and return fluid from the thermal pad. As indicated in originally filed claim 4, the pump/heat exchanger has an input connected to the thermal reservoir and connected to receive recirculation water from the thermal pad (p. 21, line 33 to p. 22, line 1):

> The fluid pump/heat exchanger having its fluid input connected to a reservoir containing cooled/heated fluid and the returning circulation water.

The circulation fluid from the thermal pad returns to the pump/heat exchanger by flowing through return inlet 12 and through air/water separator 15 (p. 17, lines 8-12):

> Net flow through the bladder 60 is achieved by creating a pressurized output flow via the pump/heat exchanger 13 with the spent water returning from the bladder 60 to the air/water separator and ultimately to the inlet side of the pump/heat exchanger 13.

(2) The disclosure explains that the pump/heat exchanger replaces a selected amount of recirculation fluid with reservoir fluid to achieve a selected recirculation fluid temperature. As described at p. 17, lines 12-19:

> The pump/heat exchanger 13, under microprocessor control, continuously displaces a precise amount of re-circulation water with water from the constant temperature reservoir to precisely maintain the temperature of the circulation water exiting the pump/heat exchanger 13. The displaced re-circulation water is returned to the reservoir via the air/water separator 15 to maintain a constant volume in the circulation system.

And as described at p. 11, lines 3-15:

> The apparatus maintains temperature control at the therapy site by a controlled dynamic mixing of cold/hot water from the reservoir with re-circulation water returning from the bladder within the heat exchanger. By using the real-time temperature information generated by the temperature sensing devices, the microprocessor controls the rate of reservoir/recirculation fluid mixing within the heat exchanger. This maintains the circulation water temperature, and thus the injury site bladder temperature. To ensure even temperature distribution at the therapy site or sites, particularly when multiple bladders are used in series, maximum flow rates and delivery pressure is maintained to minimize the difference between outgoing and returning water temperatures regardless of the heat load.

(3) The disclosure also explains that the pump/heat exchanger delivers pressurized fluid to the thermal pad to complete the fluid flow path. The pump/heat exchanger includes a pump and a heat exchanger. As indicated in originally filed claim 6, the pump has an input connected to the heat exchanger and an output connected to the thermal pad (p. 22, lines 29-33):

> said fluid pump having its fluid input connected to a heat exchanger containing controlled temperature fluid and its fluid output connected by a fluid supply tube to a bladder device.

Although not shown from the perspective of Fig. 2, the specification explains that the output of pump/heat exchanger 13 is connected to fluid outlet 11 by the tube to which thermistor 20 is attached (p. 14, lines 23-25):

> Closed loop control is affected by two thermistors 20 placed in the supply tube to the outlet disconnect 11.

We submit that, based on this disclosure, one skilled in the art can make and use the invention without undue experimentation and, therefore, the rejection should be withdrawn.

The Examiner has rejected claims 8-11 and 13 over Koewler (U.S. Patent No. 5,476,489).

Koewler, however, does not teach or suggest a thermal therapy apparatus with a heat exchanger for replacing a selected amount of circulating fluid in a recirculating fluid loop with fluid from a thermal reservoir to achieve a selected fluid temperature in the recirculating fluid loop, as now recited in independent claim 8. Koewler, instead controls the fluid temperature by varying the rate of fluid flow through the system using a variable-speed pump (col. 7, lines 18-27):

> In the cold therapy system of the present invention, temperature of the water circulating through pad 7 is controlled by the flow rate. Pump 4 has a variable-speed motor. At the highest speed, the water flow will be coldest, falling within the range of from about 38° to about 45° F. At the

> intermediate motor speed, the flowing water will have a temperature of from about 40° to about 50° F. At the lower speed of the pump, the flowing water will have a temperature falling within the range of from about 45° to about 55° F.

The portion of Koewler's cooling pad near the fluid input is always at the temperature of the cooling reservoir because the input of Koewler's cooling pad is coupled directly to the cooling reservoir. This may cause discomfort at the fluid input when the pad is used for extended periods of time. Furthermore, the temperature differential across Koewler's cooling pad increases as the pump speed is reduced to achieve the intermediate and high temperature control (i.e., at the intermediate and low pump speeds) because the fluid flow rate through the pad is reduced.

The invention now recited in claim 8, on the other hand, does not control the therapy temperature by changing the recirculation fluid flow rate. The invention instead controllably mixes the recirculation fluid with reservoir fluid to achieve the selected recirculating fluid temperature. The invention therefore allows a high pump speed to be used for different temperatures to achieve a relatively small temperature differential across the therapy site. Furthermore, unlike Koewler's system, the temperature of the fluid injected at the input of the thermal pad can be different from the temperature of the reservoir fluid, enabling a person to use the invention for extended periods of time without risk of tissue damage resulting from prolonged exposure to the temperature of the reservoir fluid.

For these reasons, the rejection over Koewler should be withdrawn.

The Examiner has rejected claims 8-18 over French (U.S. Patent No. 4,844,072).

But French, like Koewler, does not teach or suggest a thermal therapy apparatus with a heat exchanger for replacing a selected amount of circulating fluid in a recirculating fluid loop with fluid from a thermal reservoir to achieve a selected fluid temperature in the recirculating fluid loop, as now recited in independent claim 8. When cooling, French does not control the therapy temperature and, when heating, French heats the temperature of the fluid in the entire system, including the reservoir, to achieve the desired temperature at the therapy site (col. 6, lines 15-22):

> System 18 is selectively operated in either of two operating modes; a "heater off" mode for cold therapy and a "heater on" mode for heat therapy. For heat therapy, a heater 102 is selectively energized to heat the liquid to a controlled set-point temperature as will be described further below. Heater 102 is an immersible heater located in the liquid flow path, preferably inside reservoir 36 below the normal liquid level.

According to French col. 13, lines 46-61; emphasis added):

> In the "heater on" mode, controller 160 operates to heat the liquid in the system 18 to the set-point temperature selected as described above. ... <u>In the "heater off" mode, system 18 displays liquid temperature but does not control it</u>.

Thus, when applying cold therapy, French does not control the temperature of the recirculating fluid -- French merely circulates fluid between the reservoir and the therapy pad

-- and when applying heat therapy, French heats all of the fluid in the system to the desired temperature. French therefore does not even hint at replacing a selected amount of circulating fluid with fluid from the reservoir to achieve a selected fluid temperature in the recirculating fluid loop, as now recited in claim 8. As in Koewler's system, the portion of French's therapy pad near the fluid input is always at the temperature of the reservoir fluid because the input of French's therapy pad is coupled directly to the reservoir. This may cause discomfort at the fluid input when the pad is used for extended periods of time.

For these reasons, the rejection over French should also be withdrawn.

The Examiner has rejected claims 12 and 14-18 over Koewler in view of French. In particular, the Examiner has indicated that:

> It would have been obvious to one skilled in the art to use the therapy device of Koewler and modify it by adding the control mechanism as taught in French et al. in order to enhance operation of the device.

Contrary to the Examiner's assertion, however, it would not have been obvious to use French's controller with Koewler's device because the thermal therapy devices disclosed in Koewler and French operate in incompatible ways. As explained above, when cooling, French does not control the fluid temperature. Koewler, on the other hand, controls the temperature of the cooling pad by changing the fluid flow rate. The Examiner does not provide any support for his assertion that the operation of

Koewler's device would be enhanced by replacing the variable speed pump controller with French's controller. In fact, there can hardly be any motivation for replacing Koewler's controller, which controls the cooling temperature by adjusting the flow rate, with a controller that does not exert any control over the fluid temperature when cooling therapy is applied, as described in French.

In any event, neither Koewler nor French teaches or suggests a thermal therapy apparatus that includes a heat exchanger for replacing a selected amount of circulating fluid in a recirculating fluid loop with fluid from a thermal reservoir to achieve a selected fluid temperature in the recirculating fluid loop, as now recited claim 8.

The rejection over Koewler in view of French should therefore be withdrawn.

The dependent claims incorporate features of independent claim 8 and are therefore patentable for at least the same reasons.

For the above reasons, we submit that the claims are in condition for allowance and should be allowed.

Enclosed herewith is an english language translation of Gembrys (DE 33 43 664), which was cited in the information disclosure statement filed September 27, 1996. As the examiner will see, Gembrys does not teach or suggest a heat exchanger that achieves a selected fluid temperature in the recirculating fluid loop by "replacing a selected amount of circulating fluid with fluid from [the] reservoir," as now recited in claim 8. Instead,

Gembrys controls the fluid temperature in a heat transfer element (3) by alternately drawing fluid from hot and cold fluid containers 20, 21 through a switching/mixing valve 29 (see, e.g., page 7, line 19 to page 8, line 2 of the translation). Thus, Gembrys appears to teach that two fluid reservoirs, hot and cold, are needed to achieve the selected temperature; only a single reservoir is needed for the invention recited in amended claim 8.

For these reasons we ask that the claims be allowed and the application be passed to allowance.

Please charge any additional fees, or make any credits, to Deposit Account No. 06-1050.

Respectfully submitted,

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